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PROPOSED REGULATIONS

Article 1. Definitions

Section 64801.010

"Double Blind Sample" means a sample from a proficiency testing study which has not been announced to the laboratory as a proficiency testing study sample, and is received by the laboratory as if the sample was a real world sample for analysis.

Section 64801.100.

"Proficiency Testing Study" is equivalent to performance evaluation study, and means an evaluation process of environmental testing laboratories through the use of samples of unknown composition (to the laboratory), where the sample composition is known only to the provider of such samples.

Section 64801.120

"Real World Samples" mean samples collected from the environment, specifically for analysis by an environmental testing laboratory, and are not proficiency testing study samples or quality control samples.

Section 64801.123

"Reference Laboratory" is a laboratory owned and operated by a Federal or State government agency, and is capable of conducting unusual, highly specialized, complex analyses, as well as

routine environmental testing of samples for regulatory purposes.

Section 64801.125

"Representative Analytes" means various analytes that the Department or a Federal regulatory agency had selected to represent laboratory performance with a particular method in a proficiency testing study.

Section 64801.145

"Single Blind Sample" means a sample from a proficiency testing study which has been announced to the laboratory as a proficiency testing study sample for analysis.

Section 64801.160

"True Value" is the gravimetric true concentration of an analyte, or a reference value obtained from a primary standard for the analyte, in a proficiency testing study sample.

NOTE: Authority cited: Sections 100275, 100835 and 100835, ~~208, 1011 and 1012~~, Health and Safety Code. Reference: Sections 100825, 100845 and 100870, ~~1010, 1014 and 1017~~, Health and Safety Code; Section 6254.7(d), Government Code; Sections 630 and 670, Vehicle Code; Section 21, Harbors and Navigations Code.

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Article 5. Performance Evaluation Testing Process

Section 64809. Laboratory Performance Evaluation Test Requirements ~~Performance Evaluation Testing~~

(a) Each laboratory certified or applying for initial certification, amendment of certification, reinstatement, and/or renewal under the Environmental Laboratory Accreditation Program for a field-of-testing in Health & Safety Code 100860.1 shall participate in proficiency testing studies, as described in Section 64809.1, and shall analyze proficiency testing study samples in the matrix representative of the field-of-testing in which the laboratory is certified or requesting certification.

(b) Each laboratory certified or applying for initial certification, amendment of certification, reinstatement, and/or renewal under the Environmental Laboratory Accreditation Program for a field-of-testing in Health & Safety Code 100860.1 shall analyze proficiency testing study samples designated for the respective field-of-testing as described below, and obtain results that meet the acceptance criteria specified in Section 64809.2.

(1) For the field-of-testing involving drinking water microbiology, the laboratory shall participate in the Water Supply microbiology studies and/or the drinking water microbiology proficiency testing studies provided by the Department or by a third party provider.

(2) For fields-of-testing involving drinking water chemistry, the laboratory shall participate in the Water Supply chemistry studies and/or the drinking water chemistry proficiency testing studies provided by the Department or by a third party provider.

(3) For field-of-testing involving drinking water radiochemistry, the laboratory shall participate in the Water Supply radiochemistry studies and/or the drinking water radiochemistry proficiency testing studies provided by the Department or by a third party provider.

(4) For field-of-testing involving wastewater microbiology, the laboratory shall participate in the Water Pollution microbiology studies and/or the wastewater microbiology proficiency testing studies provided by the Department or by a third party provider.

(5) For fields-of-testing involving wastewater chemistry, the laboratory shall participate in the Water Pollution chemistry studies and/or the wastewater chemistry proficiency testing studies provided by the Department or by a third party provider.

(6) For the field-of-testing involving wastewater radiochemistry, the laboratory shall participate in the Water Supply radiochemistry studies and/or the wastewater radiochemistry proficiency testing studies provided by the Department or by a third party provider.

(7) For the field-of-testing involving wastewater aquatic toxicity bioassay, the laboratory shall participate in the wastewater aquatic bioassay proficiency testing studies provided by the Department or by a third party provider.

(8) For fields-of-testing involving hazardous waste chemistry, the laboratory shall participate in the RCRA studies and/or the hazardous waste chemistry proficiency

testing studies provided by the Department or by a third party provider.

(9) For the field-of-testing involving hazardous waste radiochemistry, the laboratory shall participate in the hazardous waste radiochemistry proficiency testing studies provided by the Department or by a third party provider.

(10) For the field-of-testing involving hazardous waste aquatic toxicity bioassay, the laboratory shall participate in the hazardous waste aquatic bioassay proficiency testing studies provided by the Department or by a third party provider.

(11) For the field-of-testing involving hazardous waste asbestos, the laboratory shall participate in the NIST/NVLAP bulk asbestos studies provided by the National Institute of Standards and Technology (NIST) and/or the hazardous waste asbestos proficiency testing studies provided by the Department or by a third party provider.

(12) For the field-of-testing involving food microbiology, the laboratory shall participate in the food microbiology proficiency testing studies provided by the Department or by the California Department of Food and Agriculture.

(13) For fields-of-testing involving food chemistry, the laboratory shall participate in the food chemistry proficiency testing studies provided by the Department or by the California Department of Food and Agriculture.

(14) For field-of-testing involving recreational water microbiology, the laboratory shall participate in the recreational waters microbiology proficiency testing studies provided by the Department or by a third party provider.

(15) For the field-of-testing involving shellfish microbiology, the laboratory shall participate in the shellfish microbiology proficiency testing studies provided by the U.S. Food and Drug Administration and microbiology proficiency testing studies provided by the Department. The laboratory shall also participate in the proficiency testing studies provided for the field-of-testing involving wastewater microbiology, as described in Section 64809.3, and shall comply with all requirements for the proficiency testing study.

(c) Each laboratory shall participate in proficiency testing studies at the frequencies specified in Section 64809.3 if proficiency testing study samples are available, and shall comply with other provisions specified in the same section.

(d) Each laboratory failing to obtain proficiency testing study results that meet the acceptance criteria specified in Section 64809.2, shall take corrective action(s), maintain records of such actions, and submit a corrective action summary for each failed analyte to the Department within 30 days of receipt of the evaluation report from the provider of the proficiency testing study. The corrective action summary shall include the laboratory's determination of the cause(s) for each "not acceptable" evaluation, and actions taken to improve future data quality.

NOTE: Authority cited: Sections ~~208, 1011 and 1012~~ , 100275 and 100835, Health and Safety Code. Reference: Sections ~~1015, 1017 and 1019~~ , 100850 and 100870, Health and Safety Code.

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Section 64809.1. Proficiency Testing Studies

(a) Each laboratory shall analyze proficiency testing study samples by methods routinely used on real world samples received at the laboratory for regulatory purposes.

(b) The laboratory staff member, who routinely performs analysis of real world samples that are received at the laboratory for testing for regulatory purposes, shall analyze the proficiency testing study samples.

(c) Each laboratory shall handle, process, and analyze the proficiency testing study samples as routinely conducted on real world samples received at the laboratory for testing for regulatory purposes.

(d) Each laboratory shall submit proficiency testing study results to the provider of the study samples by the closure date of the study. Submittal of study results after the study closure date shall be deemed a failed performance in said study.

NOTE: Authority cited: Section 100835, Health and Safety Code. Reference: Sections 100850, 100870, Health and Safety Code.

Section 64809.2 Proficiency Testing Study Acceptance Criteria

(a) Each laboratory, certified or applying for certification for microbiology of drinking water field-of-testing where results in a proficiency testing study require a presence/absence response, shall meet the acceptance response of present or absent as determined by the in-house laboratory of the provider.

(b) Each laboratory, certified or applying for certification for microbiology of drinking water field-of-testing where results in a proficiency testing study require enumeration, shall meet the acceptance limits at the 95% confidence level based on reference laboratory data, or as required by the National Environmental Laboratory Accreditation Program if reference laboratory data is not available.

(c) Each laboratory, certified or applying for certification for inorganic chemistry of drinking water field-of-testing shall meet the acceptance criteria as specified in the Code of Federal Regulations, July 1, 2001, volume 40, part 141.23(k)(3)(ii). For proficiency testing study analytes that do not appear in this Federal regulation, each laboratory shall meet the acceptance limits at the 95% confidence level based on reference laboratory data, or as required by the National Environmental Laboratory Accreditation Program if reference laboratory data is not available. For proficiency testing study analytes that do not appear in Federal regulations or are not required by the National Environmental Laboratory Accreditation Program, each laboratory shall meet the acceptance limits at the designated per cent from the true value in Table 1 of appendix A.

(d) Each laboratory, certified or applying for certification for toxic chemical elements

of drinking water field-of-testing shall meet the acceptance criteria as specified in the Code of Federal Regulations, July 1, 2001, volume 40, parts 141.23(k)(3)(ii) and 141.89(a)(1)(ii). For proficiency testing study analytes that do not appear in this Federal regulation, each laboratory shall meet the acceptance limits at the 95% confidence level based on reference laboratory data, or as required by the National Environmental Laboratory Accreditation Program if reference laboratory data is not available. For proficiency testing study analytes that do not appear in Federal regulations or are not required by the National Environmental Laboratory Accreditation Program, each laboratory shall meet the acceptance limits at the designated per cent from the true value in Table 1 of appendix A.

(e) Each laboratory, certified or applying for certification for volatile organic chemistry of drinking water field-of-testing shall meet the acceptance criteria as specified in the Code of Federal Regulations, July 1, 2001, volume 40, part 141.24(f)(17)(i) for 85% of the designated analytes within the specified acceptance limits. Each laboratory shall also meet the acceptance criteria as specified in the Code of Federal Regulations, July 1, 2001, volume 40, part 141.24(f)(17)(ii) for vinyl chloride. For proficiency testing study analytes that do not appear in this Federal regulation, each laboratory shall meet the acceptance limits at the 95% confidence level based on reference laboratory data, or as required by the National Environmental Laboratory Accreditation Program if reference laboratory data is not available. For proficiency testing study analytes that do not appear in Federal regulations or are not required by the National Environmental Laboratory Accreditation Program, each laboratory shall meet the acceptance limits at the designated per cent from the true value in Table 1 of appendix A.

(f) Each laboratory, certified or applying for certification for semi-volatile organic chemistry of drinking water field-of-testing shall meet the acceptance criteria as specified in the Code of Federal Regulations, July 1, 2001, volume 40, part 141.24(h)(19)(i). For proficiency testing study analytes that do not appear in this Federal regulation, each laboratory shall meet the acceptance limits at the 95% confidence level based on reference laboratory data, or as required by the National Environmental Laboratory Accreditation Program if reference laboratory data is not available. For proficiency testing study analytes that do not appear in Federal regulations or are not required by the National Environmental Laboratory Accreditation Program, each laboratory shall meet the acceptance limits at the designated per cent from the true value in Table 1 of appendix A.

(g) Each laboratory, certified or applying for certification for radiochemistry of drinking water field-of-testing shall meet the acceptance limits at the 95% confidence level based on data from a reference laboratory, or as required by the National Environmental Laboratory Accreditation Program if reference laboratory data is not available.

(h) Each laboratory, certified or applying for certification for microbiology of wastewater field-of-testing shall meet the acceptance limits at the 99% confidence level based on reference laboratory data, or as required by the National Environmental Laboratory Accreditation Program if reference laboratory data is not available.

(i) Each laboratory, certified or applying for certification for inorganic chemistry of wastewater, toxic chemical elements of wastewater, volatile organic chemistry of wastewater, and semi-volatile organic chemistry of wastewater fields-of-testing shall

meet the acceptance limits at the 99% confidence level based on reference laboratory data. For proficiency testing study analytes that do not appear in Federal regulations or are not required by the National Environmental Laboratory Accreditation Program, each laboratory shall meet the acceptance limits at the designated per cent from the true value in Table 2 of appendix A.

(j) Each laboratory, certified or applying for certification for radiochemistry of wastewater field-of-testing shall meet the acceptance limits at the 95% confidence level based on data from a reference laboratory, or as required by the National Environmental Laboratory Accreditation Program if reference laboratory data is not available.

(k) Each laboratory, certified or applying for certification for whole effluent toxicity of wastewater field-of-testing shall meet the acceptance limits at the 95% confidence level based on reference laboratory data.

(l) Each laboratory, certified or applying for certification for inorganic chemistry and toxic chemical elements of hazardous waste, volatile organic chemistry of hazardous waste, and semi-volatile organic chemistry of hazardous waste fields-of-testing shall meet the acceptance limits at the 99% confidence level based on reference laboratory data, or as required by the National Environmental Laboratory Accreditation Program if reference laboratory data is not available.

(m) Each laboratory, certified or applying for certification for radiochemistry of hazardous waste field-of-testing shall meet the acceptance limits at the 99% confidence level based on data from a reference laboratory, or as required by the National

Environmental Laboratory Accreditation Program if reference laboratory data is not available.

(n) Each laboratory, certified or applying for certification for toxicity bioassay of hazardous waste field-of-testing shall meet the acceptance limits at the 95% confidence level based on reference laboratory data.

(o) Each laboratory, certified or applying for certification for bulk asbestos analysis of hazardous waste field-of-testing shall meet the acceptance criteria specified by the National Institute of Science & Technology, National Voluntary Laboratory Accreditation Program for bulk asbestos.

(p) Each laboratory, certified or applying for certification for shellfish sanitation field-of-testing shall meet the acceptance criteria as specified in the U.S. Food & Drug Administration Shellfish Laboratory Quality Assurance Program of 1999.

(q) Each laboratory, certified or applying for certification for organic chemistry of pesticide residues in food (measurements by MS techniques), and organic chemistry of pesticide residues in food (excluding measurements by MS techniques) fields-of-testing shall meet the acceptance limits at the 99% confidence level based on reference laboratory data.

(r) Each laboratory, certified or applying for certification for microbiology of recreational water field-of-testing shall meet the acceptance limits at the 99% confidence level based on reference laboratory data.

(s) A laboratory result determined as a false negative or false positive for an analyte in a proficiency testing study shall be evaluated as "not acceptable" for that particular analyte.

(t) A laboratory testing for a group of organic compounds by a single method shall successfully analyze 85% or greater of representative analytes (whether present or absent in the proficiency testing study) by the respective method. If the laboratory successfully analyzes less than 100% of the representative analytes, then the laboratory shall participate in a subsequent proficiency testing study within a 12-month period, successfully analyze 85% or greater of representative analytes (whether present or absent in the proficiency testing study) by the respective method, and obtain acceptable performance for those analytes which were evaluated as “not acceptable” in the previous study.

NOTE: Authority cited: Section 100835, Health and Safety Code. Reference: Sections 100850 and 100870, Health and Safety Code.

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APPENDIX A

Table 1

Table 1 only applies to sections 64809.2(c) through (f), and provides the acceptance criteria for scoring results from participants in a drinking water proficiency testing study for various types of analytes that are not specified in Federal regulations, or are not required by the National Environmental Laboratory Accreditation Program, or are without reference laboratory data:

Types of Analytes	**Acceptance Criteria**
Inorganic chemistry analytes	±20% for >10ppm; ±30% for ≤10ppm
Perchlorate	±15% for ≥10ppm; ±25% for <10ppm
UV254	±30%
Metals	±20% for ≥10ppb; ±30% for <10ppb
Semi-volatile organic compounds	±50%
PCBs	±60%
Pesticides / Herbicides	±60%
Volatile organic compounds	±20% for ≥10ppb; ±40% for <10ppb

Table 2

Table 2 only applies to section 64809.2(i), and depicts the acceptance criteria for scoring results from participants in a wastewater proficiency testing study for various types of analytes that are not specified in Federal regulations, or are not required by the National Environmental Laboratory Accreditation Program, or are without reference laboratory data:

Types of Analytes	**Acceptance Criteria**
Inorganic chemistry analytes	±30%
Metals	±30%
asbestos	±150%
Physical properties	±30%
Semi-volatile organic compounds	±70%
PCBs	±70%
Pesticides / Herbicides	±80%

Section 64809.3. Frequency of Participation and Other Provisions

(a) A laboratory applying for certification in a field-of-testing shall participate in a minimum of one, but not more than two proficiency testing studies prior to issuance of the certificate. Where two performance evaluation studies are attempted, the studies shall be performed at a minimum of 30-days apart from the date of the first study closure and the date of commencement of the second study. The laboratory shall successfully participate in one proficiency testing study by the 240th day (sixth month) from the date of the Department's receipt of application for each analyte (group-of-analytes, species or matrix) and by each method for which the laboratory is applying for certification.

(b) A laboratory certified or applying for renewal of certification shall participate in a minimum of one, but not more than two proficiency testing studies within a 12-month period, unless otherwise required below. Where two proficiency testing studies are attempted, the studies shall be no less than 240 days (six months) apart from the date of the first study closure and the date of commencement of the second study. The laboratory shall successfully participate in a proficiency testing study for each analyte (group-of-analytes, species or matrix) and by each method for which the laboratory is certified or applying for certification.

(1) For fields-of-testing involving drinking water, wastewater, or recreational water microbiology, successful participation shall involve analyses of all samples provided for the method, and obtaining results meeting the acceptance criteria in Section 64809.2 for all analytes (or group-of-analytes) by each method for which the laboratory is certified.

(2) For fields-of-testing involving food chemistry, a laboratory shall participate in all

proficiency testing studies provided every 12 months. In each study, a laboratory shall use each method for which the laboratory is certified.

(3) For fields-of-testing involving aquatic toxicity bioassay in wastewater or hazardous waste, a laboratory shall participate in all proficiency testing studies provided every 12 months, not to exceed two within a 12-month period. In each study, the laboratory shall use all methods for which the laboratory is certified to test each species with the study samples.

(c) No laboratory certified or seeking certification pursuant to this chapter shall submit results for evaluation in a proficiency testing study where the Department is the recipient of the evaluated results, if the laboratory has financial interest, familial relationship, or contractual agreement in consultative capacity with the person or in the entity that provides the proficiency testing study samples.

NOTE: Authority cited: Section 100835, Health and Safety Code. Reference: Section 100870, Health and Safety Code.

Section 64809.4. Sanctions

(a) A certified laboratory, or a laboratory that has applied for renewal of its certificate, and has unacceptable performances for a method with the same analyte, group-of-analytes, species, or matrix in two consecutive single-blind proficiency testing studies within a 12-month period shall be subject to denial of certification or revocation of its certificate in whole or in part.

(b) A certified laboratory, that has not participated in available single-blind proficiency testing studies within a 12-month period, shall be subject to revocation of its certificate for the field-of-testing.

(c) A certified laboratory, rated as performing unacceptably in a double-blind proficiency testing study for a method with the same analyte, group-of-analytes, species, or matrix that was previously evaluated as “not acceptable” in a single-blind proficiency testing study, shall be subject to revocation of its certificate in whole or in part.

(d) A laboratory in violation of section 64809.2(t) shall be subject to revocation of its certificate for the method.

NOTE: Authority cited: Section 100835, Health and Safety Code. Reference: Section 100850, Health and Safety Code.